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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/862,710	05/23/2001	Chirag B. Shah	P296 DIV1	1806
28390	7590	03/24/2004	EXAMINER	
MEDTRONIC AVE, INC. 3576 UNOCAL PLACE SANTA ROSA, CA 95403			ROBERTSON, JEFFREY	
			ART UNIT	PAPER NUMBER

1712

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/862,710

Applicant(s)

SHAH ET AL.

Examiner

Jeffrey B. Robertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-13 and 60-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-8,10-12,60-65 and 67-69 is/are rejected.
- 7) ☒ Claim(s) 9,13,66 and 70-78 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 4-8, 10-12, 60-65, and 67-69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-6, and 10-13 of U.S. Patent No. 6,248,127. Although the conflicting claims are not identical, they are not patentably distinct from each other because although claims 1 and 60 are directed to coatings, they are coated onto a medical device substrate. Claim 1 of the '127 patent is directed to a medical device, but the medical device is coated with the same coating as set forth in claims 1 and 60 of the instant application. In effect both claims are directed to coated medical devices.

Claims 1 and 60 of the instant application and claim 1 of the '127 patent contain the exact same coating. Besides the fact that claim 1 of the instant application is directed to a coating and claim 1 of the '127 patent is directed to a medical device, the

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only difference between the subject matter of claim 1 of the instant application and claim 1 the '127 patent is that claim 1 of the instant application requires that the coating be covalently bound to the medical device. For claim 60, in addition to the differences set forth for claim 1, claim 60 uses the transitional phrase "consisting essentially of". Although covalent bonding is not explicitly set forth in claim 1 of the '127 patent, the examiner's position is that it is inherent that these coatings covalently bond to the medical device due to the presence of the silane groups. For claim 60, although the transitional language is different, the subject matter overlaps to such a great extent with claim 1 of the '127 patent that a clear indication of a difference between the claims is not readily apparent.

For claims 4 and 61 of the instant application, claim 10 of the '127 patent specifies an isocyanate functional group.

For claims 5, 11, 62, and 68 of the instant application, claim 13 of the '127 patent sets forth that the biopolymer is heparin-tridodecylmethylammonium chloride. Although the complete limitations of claim 13 of the '127 patent are not the same as claims 11 and 68 of the instant application, it would have been obvious to one of ordinary skill in the art to utilize a biopolymer that is heparin-tridodecylmethylammonium chloride as set forth in the claim of the patent. The motivation would have been that the '127 patent specifically sets forth this biopolymer as a particular species of a genus of biopolymers to use in the coated medical devices.

For claims 6 and 63 of the instant application, claims 5 and 12 of the '127 patent set forth the same Markush group. Although the complete limitations of claims 5 and 12

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of the '127 patent are not the same as claims 6 and 63 of the instant application, it would have been obvious to one of ordinary skill in the art to utilize a biopolymer from the Markush group set forth in the claims of the patent. The motivation would have been that the '127 patent specifically sets forth these biopolymers as a particular species of a genus of biopolymers to use in the coated medical devices.

For claims 7, 8, 10, 64, 65, and 67 of the instant application, in claim 4 of the '127 patent, heparin is set forth as a biopolymer. Although the complete limitations of claim 4 of the '127 patent are not the same as claims 8 and 65 of the instant application, it would have been obvious to one of ordinary skill in the art to utilize heparin as a biopolymer as set forth in the claim of the patent. The motivation would have been that the '127 patent specifically sets forth this biopolymer as a particular species of a genus of biopolymers to use in the coated medical devices. For claims 7, 10, 64, and 67, the examiner's position is that heparin inherently contains hydroxyl groups and possesses thromboresistance.

For claims 12 and 69 of the instant application, claim 6 of the '127 patent sets forth the same additives for the coating as in claims 12 and 69. Although the complete limitations of claim 6 of the '127 patent are not the same as claims 12 and 69 of the instant application, it would have been obvious to one of ordinary skill in the art to utilize additives set forth in the claim of the patent. The motivation would have been that the '127 patent specifically sets forth these additives to use in the coated medical devices.

Response to Arguments

3. Applicants' arguments with respect to the claims have been considered and are persuasive in light of applicant's amendments to the claims. However, the examiner notes the new ground(s) of rejection as set forth above.

Allowable Subject Matter

4. Claims 9, 13, 66, and 70-78 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

5. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

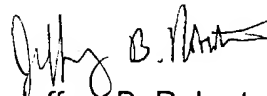
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey B. Robertson whose telephone number is (571) 272-1092. The examiner can normally be reached on Mon-Fri 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jeffrey B. Robertson
Primary Examiner
Art Unit 1712

JBR